

MEMORANDUM OF LAW

EXHIBIT B

DECLARATION OF DR. EDWARD A. LEMMO

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

Stanley H. Kremen,
Attorney at Law
4 Lenape Lane
East Brunswick, New Jersey 08816
(732) 593-7294
Attorney for the Plaintiff

Keith Altman
The Law Office of Keith Altman
38228 West 12 Mile Road, Suite 375
Farmington Hills, Michigan 48334
(248) 987-8929
Attorney for the Plaintiff

TRUTEK CORP.,
Plaintiff,

v.

CIVIL ACTION No. 2:21-cv-10312-SJM-RSW

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender
neutral fictitious names, and ABC
CORPORATION 1 through 10
(fictitious names).

Defendants.

**DECLARATION OF DR. EDWARD A. LEMMO IN SUPPORT OF
PLAINTIFF'S MOTION FOR LEAVE TO FILE AMENDED COMPLAINT**

I, Edward A. Lemmo, being of full age, hereby depose and say under pains and penalties of perjury under the laws of the United States and the State of Michigan:

1. I am a citizen of the United States of America, and I reside in the State of New York.

2. I received a B.S. degree in Chemistry in 1973 from St. Francis College in Brooklyn, New York, and both an M.S. and Ph.D. in Nutrition Science in 1977 and 1979, respectively, from Rutgers University in New Brunswick, New Jersey. My resume is appended to this declaration.
3. I was retained to review United States patents that were assigned to Nanobio Corporation as well as information contained on past and present websites owned by BlueWillow Biologics, Inc. (www.bluewillow.com), and to opine on various aspects of BlueWillow's and Nanobio's vaccine technology.
4. I reviewed the following Nanobio patents:
 - a. U.S. Patent No. 8,226,965 B2, issued on July 24, 2012 to James R. Baker, Jr., *et.al.*, entitled, "Methods of Treating Fungal, Yeast And Mold Infections."
 - b. U.S. Patent No. 8,703,164 B2, issued on April 22, 2014 to Ted C. Annis, *et.al.*, entitled, "Compositions For Inactivating Pathogenic Microorganisms, Methods of Making, the Compositions, and Methods of Use Thereof."
 - c. U.S. Patent No. 9,131,680 B2, issued on September 15, 2015 to Theodore C. Annis, *et.al.*, entitled, "Compositions For Inactivating Pathogenic Microorganisms, Methods of Making, the Compositions, and Methods of Use Thereof."
 - d. U.S. Patent No. 9,144,606 B2, issued on September 29, 2015 to James R. Baker, Jr., *et.al.*, entitled, "Nanoemulsion Influenza Vaccine."
 - e. U.S. Patent No. 9,492,525 B2, issued on November 15, 2016 to Ali I. Fattom, *et.al.*, entitled, "Human Respiratory Syncytial Virus Vaccine."
 - f. U.S. Patent No. 9,561,271 B2, issued on February 7, 2017 to Ali. I. Fattom, *et.al.*, entitled, "Nanoemulsion Respiratory Syncytial Virus (RSV) Subunit Vaccine."

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- 1 g. U.S. Patent No. 10,206,996 B2, issued on February 19, 2019 to Ali. I.
- 2 Fattom, *et.al.*, entitled, "Herpes Simplex virus Nanoemulsion Vaccine."
- 3 h. U.S. Patent No. 10,525,121 B2, issued on January 7, 2020 to Tarek
- 4 Hamouda, *et.al.*, entitled, "Nanoemulsion Influenza Vaccine."
- 5 i. U.S. Patent No. 10,596,251 B2, issued on March 24, 2020 to Ali I.
- 6 Fattom, *et.al.*, entitled, "Nanoemulsion Respiratory Syncytial Virus
- 7 (RSV) Subunit Vaccine."
- 8 5. I also reviewed the initial Complaint filed in the above captioned matter by
- 9 Plaintiff, Trutek Corp., on February 10, 2021, and in particular Exhibits 1
- 10 and 2 thereto. These two exhibits purport to represent digital snapshots of
- 11 portions of BlueWillow's website on the day the initial Complaint was filed.
- 12 6. I further reviewed the currently existing BlueWillow website
- 13 (www.bluewillow.com). I can attest to the fact that the exhibit appended to
- 14 the concurrently filed Declaration of Stanley H. Kremen is an accurate digital
- 15 snapshot of the BlueWillow website as it exists today. Therefore, since the
- 16 exhibit is being submitted by Mr. Kremen, it is unnecessary for me to attach
- 17 that exhibit to this declaration.
- 18 7. The currently existing BlueWillow website refers to scientific publications in
- 19 sections labeled:
- 20 a. Intranasal Nanoemulsion Vaccines; and
- 21 b. Nanotechnology-Based Dermatology and Anti-Infective Applications.
- 22 c. I reviewed all of the scientific publications cited therein.
- 23 8. In addition, I reviewed other scientific publications regarding nanoemulsions.
- 24 Among them is an article by Matthew E. Helgeson entitled, "*Colloidal*
- 25 *behavior of nanoemulsions: Interactions, structure, and rheology*," Current
- 26 Opinion in Colloid & Interface Science 25 (2016) 39–50.
- 27 9. Finally, I reviewed United States Patent No. 8,163,802 issued to Ashok Wahi
- 28 on April 24, 2012 and assigned to Plaintiff, Trutek Corp.

1 10. It is my understanding that BlueWillow Biologics, Inc. (a Delaware
2 corporation) is a successor business entity to Nanobio Corporation (a
3 Michigan corporation).

4 11. Based on my education and experience, I am very familiar with technology
5 associated with, *inter alia*, nanoemulsions, surfactants, adjuvants,
6 electrostatic charges, cationic agents, biocidal agents, biocides, and
7 preservatives.

8 12. All of the vaccines disclosed in the Nanobio patents and on the BlueWillow
9 website are intended for nasal administration.

10 13. Nanoemulsions are oil-in-water emulsions that are stabilized by emulsifying
11 agents. They are also referred to as ultrafine emulsions. They exist as
12 extremely small sub-micron sized droplets. Nanoemulsions are widely used
13 in applications such as food products, cosmetics, and pharmaceuticals.
14 Nanoemulsions may be engineered to improve the biological accessibility of
15 bioactive molecules that are either entombed within them or maybe
16 consumed alongside them. Nanoemulsions exhibit remarkable droplet
17 stability due to their nanoscopic dimensions. By their very nature,
18 nanoemulsion droplets exhibit an electrostatic charge which causes them to
19 repel one-another. If the nanodroplets are not electrostatically charged, they
20 would coalesce into a single liquid mass.

21 14. The vaccines described in the Nanobio patents have two components: (1) a
22 vaccine component and (2) a nanoemulsion component.

23 15. All of the vaccines disclosed in the Nanobio patents, the BlueWillow
24 website, and the scientific publications referred to on that website, are
25 contained within nanoemulsion adjuvants. Therefore, regardless of the
26 specific nature of the vaccine components, because they all contain
27 nanoemulsions, the vaccines all exhibit an electrostatic charge.

28 16. Embodiments of the nanoemulsion components of the vaccines disclosed in

1 the Nanobio patents include cationic surfactants. These are positively
2 charged cationic agents.

3 17. Further, embodiments of the nanoemulsion components of the vaccines
4 disclosed in the Nanobio patents include preservatives. Preservatives are all
5 biocidal agents. Among the preservatives listed as being suitable is
6 benzalkonium chloride.

7 18. In summary, from my review of the aforementioned Nanobio patents, the
8 BlueWillow website, and the aforementioned scientific publications, it is my
9 opinion that:

- 10 a. the BlueWillow vaccines probably utilize the technology disclosed in the
11 Nanobio patents;
12 b. the BlueWillow vaccines are intended for nasal administration;
13 c. because the BlueWillow vaccines contain nanoemulsions, they exhibit an
14 electrostatic charge;
15 d. the BlueWillow vaccines probably contain cationic agents; and
16 e. the BlueWillow vaccines probably contain biocidal agents.

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18 I declare that the statements made by me above are true. I understand that I
19 am subject to the penalties of perjury for false representations according to the laws
20 of the United States and the State of Michigan.

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22 Dated: May 2, 2022

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25 Dr. Edward A. Lemmo
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Edward A. Lemmo, Ph.D.
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Staten Island, New York 10309
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EDUCATION

Ph.D. Nutrition Science, Rutgers University, New Brunswick, NJ (1979)
M.S. Nutrition Science, Rutgers University, New Brunswick, NJ (1977)
B.S. Chemistry, St. Francis College, Brooklyn, NY (1973)

EXECUTIVE TRAINING COURSES

Executive Leadership Program, Princeton, NJ
Time Management Skills, Teaneck, NJ
Media Communication Skills, New York City, NY

EMPLOYMENT EXPERIENCE

2007-Present **Consumer Healthcare Corporate Consultant**
Self-employed Consultant - Consumer Healthcare

2005-2007 **BioBalance Corporation**, New York, NY
Vice President, Product Development

Person primarily responsible for investigating its probiotic product PROBACTRIX™ to be used for treating pouchitis and other gastrointestinal disorders. Probiotic products are an optional alternative to the probiotic Lactobacillus acidophilus. In charge of all scientific product evaluation conducted at company headquarters.

1999-2005 **Wyeth Consumer Healthcare**, Leonia and Madison, NJ
Vice President, Product Development

Division of American Home Products
Formerly Whitehall-Robbins Consumer Healthcare

Managed product development for SOLGAR®, and contributed towards CENTRUM®, and CALTRATE®, brands. Responsible role in scientific affairs and new business

development opportunities. Further, responsible for evaluation of acquisition of new business entities.

1992-1999

General Nutrition Centers, Inc., Pittsburg, PA
Director, Nutritional Sciences

Analyzed safety of amino acid products for presentation to the FDA and FTC and other U.S. government agencies. Evaluated and made recommendations regarding nutritional and homeopathic products. Performed quality assurance activities related to label claims and product safety. Responsible for introduction of the new PRO-PERFORMANCE sports nutrition product line into the GNC retail marketplace.

In 1993, for Quigley Corporation, I evaluated the safety and efficacy of Cold-EEZE[®] zinc lozenges to be used to shorten a common cold as a possible line of homeopathic products exclusively marketed by GNC.

1989-1992

Pall Biomedical Products, Glen Cove, NY
Marketing Manager

Responsible for marketing activities of Intravenous filtration devices, and Heat and Moisture exchange respiratory products. Wrote all scientific evaluation documents related to Heat and Moisture Exchange respiratory product for presentation to anesthesiologists regarding prevention of injury from patients breathing cold dry gas during surgery. Developed scientific presentations, videos, and product marketing material for use by healthcare professionals.

1984-1989

ICN Pharmaceuticals, Costa Mesa, CA
Director of Nutritional Technology

Faraday Laboratories Division

Product development of nutritional supplements for use by chiropractic and alternative health practitioners throughout the United States and Canada. Product brands included Nutridyn[®] and Sivad Bioresearch[®]. Responsible for new product development, wrote technical literature, and prepared and delivered scientific educational presentations to practitioners at chiropractic colleges and chiropractic meetings.

1976-1977

**Pharmacia Laboratories, Piscataway, NJ
Clinical Trials Coordinator**

Assisted veterinarian in analysis of equine blood samples. Performed evaluation analysis of HEALON[®] products comprising hyaluronic acid, and their effect on tissues.

CORPORATE CONSULTING EXPERIENCE

2011

**Matrixx Initiatives, Inc., Princeton, NJ
Scientific Affairs Consultant**

Performed research associated with ZICAM[®] oral zinc product. Provided guidance for coordinating research trials. Managed human efficacy clinical trials.

1998-1999

**Church & Dwight, Princeton, NJ
Scientific Advisor**

Evaluated consumer healthcare products. Explored and determined market for magnesium based organo-metallic agents for use in dietary supplements.

1998-1999

IVC Industries, Freehold, NJ

IVC is a contract manufacturer of generic vitamins. Responsible for new product development. Assisted the marketing staff with product label claims.

1996

Nutrition 21, Purchase, NY

Company is a supplier to GNC. Performed consulting work regarding their products.

1996

Nutramerica, Lincoln Park, NJ

Technical advisor for the development of a dietary supplement product line.

CORPORATE CONSULTING EXPERIENCE (continued)

1996 **American Vitamin**, Ramsey, NJ

Company is a contract manufacturer. Performed new product development and assistance with evaluation of raw materials from India.

COLLEGE TEACHING EXPERIENCE

2013-2018 **Touro College**, New York City, NY

Taught in nursing school. Courses included pathophysiology, genetics, anatomy and physiology and tutored microbiology

2008-2014 **University of Medicine & Dentistry of New Jersey (UMDNJ)**, Newark, NJ

Taught in nutrition program. Courses included general chemistry, anatomy and physiology, biochemistry, and microbiology.

1977 and **New York University**, New York, NY

2000-2003 Taught in graduate nutrition program, vitamin and mineral metabolism

2011-2012 **Cedar Crest College**, Allentown, PA

Taught courses in nutritional biochemistry and metabolism.

1984-1989 **University of New Haven**, West Haven, CT

Taught graduate level course in vitamin and mineral nutrition.

1974-1984 **Brooklyn College, CUNY**, Brooklyn, NY
Assistant Professor

Taught nutrition courses to pre-medical and nutrition students.

1973-1977 **Rutgers University**, Piscataway, NJ

Taught general biology lab and mineral metabolism.